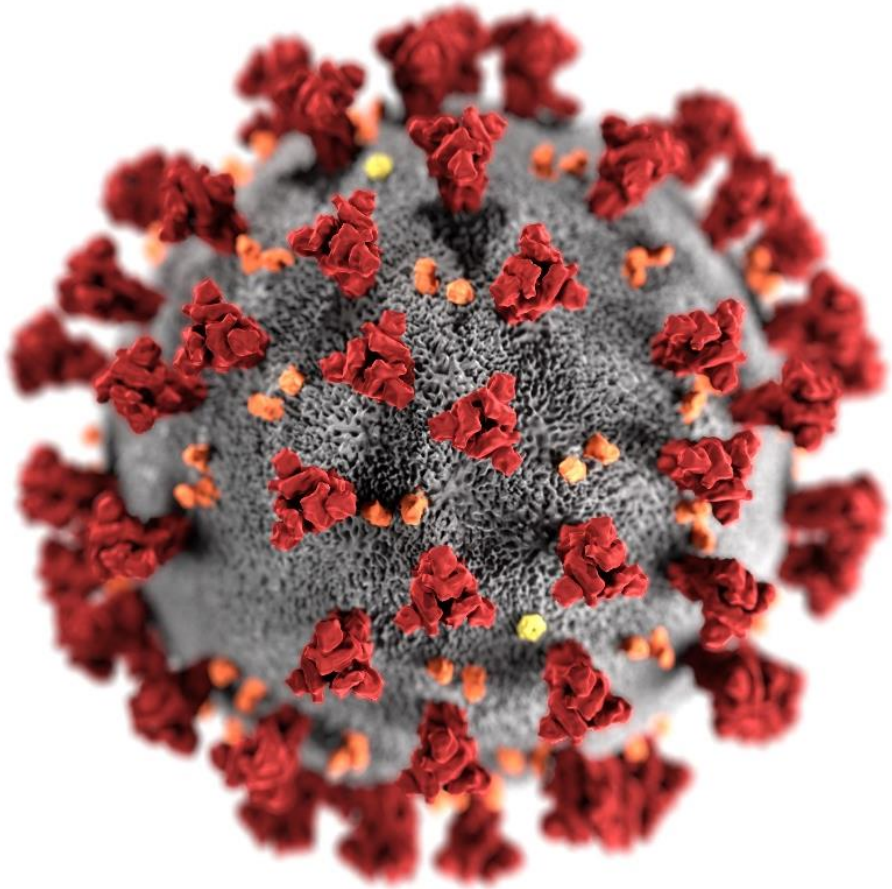
ACIP COVID-19 Vaccines



Work Group interpretations of data

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ACIP Meeting

October 30, 2020

Prior infection

Summary of Work Group interpretation:
COVID-19 vaccine and Prior infection

- Await data from Phase III trials for any possible vaccine-associated enhanced disease or reactogenicity after prior infection
- In the absence of concerning data from Phase III trials:
  - PCR +
  - Antigen +
  - Antibody +

  → Not a contraindication to receive COVID-19 vaccine
- Any vaccine recommendations that rely on knowledge of prior immunity/antibody testing would be difficult to implement

Pregnant and Breastfeeding Women

Summary of Work Group interpretation:
COVID-19 vaccine and Breastfeeding Women in Tier 1a

- Most Work Group members agreed that breastfeeding would not be a contraindication to receive a COVID-19 vaccine
  - Need to be evaluated for each vaccine, especially if any live virus/vector vaccines are authorized/licensed

Summary of Work Group interpretation:
COVID-19 vaccine and Pregnant Women in Tier 1a

- Limited data on pregnancy expected from Phase III trials
- Work Group did not reach a consensus
- Majority felt that if a woman is recommended to receive the vaccine in an early allocation phase, pregnancy should be a **precaution**, but not a contraindication to receive a COVID-19 vaccine
  - Emphasizing need to allow women to make an informed decision, providing all current knowledge of COVID-19 vaccines/platforms with pregnancy and risk of disease

Summary of Work Group interpretation:
COVID-19 vaccine and Pregnant Women in Tier 1a

- Additional situation: Pregnancy diagnosed after receipt of first dose of COVID-19 vaccine

- Majority of Work Group felt that the second dose could be given at the recommended interval
  - Minority opinion: Postponing second dose until second trimester or until after pregnancy
  - Emphasizing need to allow women to make an informed decision

Modeling

Summary of Work Group interpretation:
Modeling data

- Differences among 3 strategies is minimal
  - Ethical principles and implementation considerations may greatly contribute to selecting the optimal sequence in Phase Ib
- Largest impact in averted deaths and infections is the timing of vaccine introduction in relation to increases in COVID-19 cases
  - Emphasizes the need to continue non-pharmaceutical interventions (e.g. wearing a mask, social distancing) while we await available vaccine
- Many factors will inform interpretation of modeling data and allocation decisions
  - VE in older adults
  - Vaccine's ability to prevent severe disease or transmission
  - If the goal is to prevent greatest number of infections or greatest number of deaths

Clinical Trial Data

Immunogenicity and Safety Information Reviewed by Work Group

NVX-CoV2373 (Novavax) N=131

- **Immunogenicity**
  - Neutralizing antibodies (wild-type neutralization assay titers) and binding antibodies (ELISA) measured 14 days post-dose 2
  - Responses similar to or exceeded convalescent sera comparison
  - Th1-biased CD4+ T-cell response
  - **5µg** dose + Matrix-M1 selected for Phase III clinical trials

- **Safety**
  - Local and systemic symptoms followed for 7 days post-vaccination
    - Headache, fatigue and myalgia most common symptoms reported
  - Reactogenicity symptoms higher after second dose
  - No vaccine-related serious adverse events (SAEs) reported

Protein Subunit Vaccine

Immunogenicity and Safety Information Reviewed by Work Group

Ad26.COV2.S (Janssen) N=775

- **Immunogenicity**
  - Neutralizing antibodies (wild-type virus neutralization antibody titers) and binding antibodies (ELISA) measured 28 days post-dose 1
  - Responses similar to human convalescent sera
  - CD4+ and CD8+ T cell response demonstrated
  - Th1-biased CD4+ T-cell response
  - **$5x10^{10}$** viral particle **single** dose of Ad26.COV2.S selected for Phase III clinical trials

- **Safety**
  - Local and systemic symptoms followed after administration
    - Fatigue, headache and pain most common
  - Reactogenicity symptoms lower in older population (≥65 years)

Plans for Phase III

- Both vaccine candidates planning/enrolling large Phase III efficacy trials (30,000-60,000 people)
- Primary endpoints: symptomatic, virologically confirmed COVID-19 disease
- Attempting to enroll diverse populations:
  - Race and ethnicity
  - Age (<65 years and ≥65 years of age)
  - Underlying medical conditions

Implementation/Distribution

- Diverse cold chain, implementation requirements
- Novavax (NVX-CoV2372): 2 doses given 21 days apart, vials stored at 2-8^{o}C
- Janssen (Ad26.COV2.S): Single dose, vials stored at -20^{o}C long term, with 2-8^{o}C for 3 months

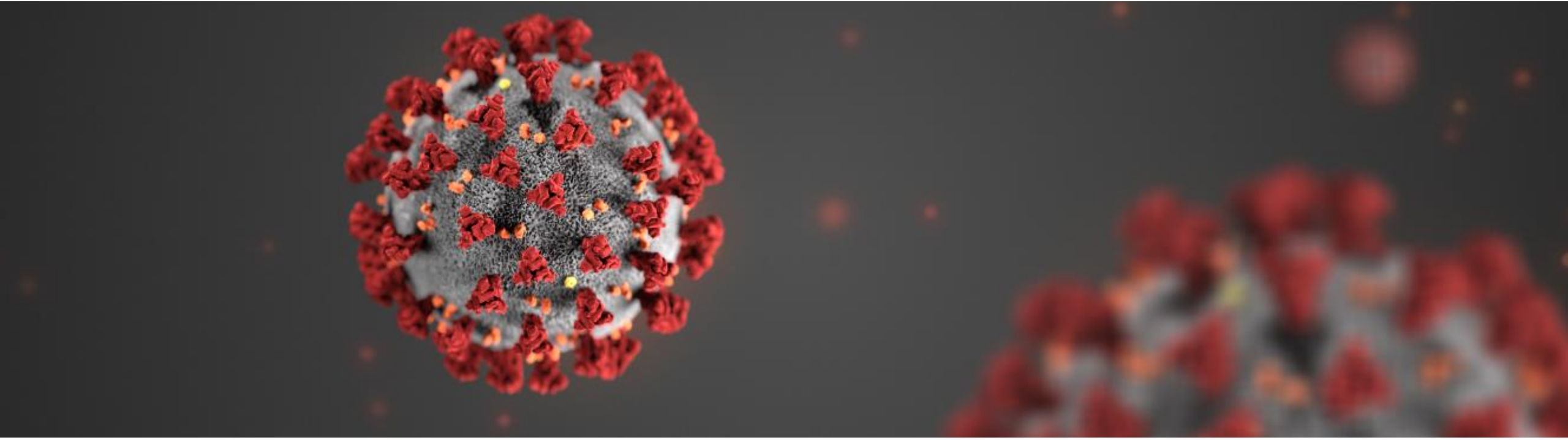
Work Group Interpretation

- Phase I/II data from the vaccines show induction of binding and neutralizing antibodies as well as T-cell responses, favorable safety/reactogenicity profile, supporting advance to Phase III trials
- Both platforms with prior experience from other vaccines
- Safety pauses are expected with large clinical trials, indicate the process is working appropriately

Work Group Interpretation:

Current Phase III Clinical Trials

- Importance of enrolling **diverse** study participants
- Importance of harmonizing safety and efficacy **endpoints** across all Phase III trials to the extent possible
- Need to report **maternal** and **fetal** outcomes for women who become pregnant during the clinical trials
- Support FDA's guidance for ensuring that Phase III trials conduct **ongoing** assessment of long-term safety and efficacy, and that issuance of an EUA is not grounds to unblind follow-up in an ongoing clinical trial



For more information, contact CDC
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Thank you

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.